



Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
Information Disclosure Statement By Applicant		Applicant:	
<i>Page 1 of 23</i> (Use Several Sheets if Necessary)		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
U.S. Patent Documents			

Examiner Initial	No.	Patent No.	Date	Patentee	Class	Sub-Class	Filing Date
<i>SSL</i>		6,921,527	07/2005	Platz, et al.			
		6,893,657	05/2005	Roser, et al.			
		6,825,031	11/2004	Franks, et al.			
		6,811,792	11/2004	Roser, et al.			
		6,797,258	09/2004	Platz, et al.			
		6,752,893	06/2004	Frieder, et al.			
		6,737,066	05/2004	Moss			
		6,737,045	05/2004	Patton, et al.			
		6,685,967	02/2004	Patton, et al.			
		6,681,767	01/2004	Patton, et al.			
		6,673,335	01/2004	Platz, et al.			
		6,655,379	12/2003	Clark, et al.			
		6,649,911	11/2003	Kawato			
		6,630,169	10/2003	Bot, et al.			
		6,592,904	07/2003	Platz, et al.			
		6,589,560	07/2003	Foster, et al.			
		6,586,006	07/2003	Roser, et al.			
		6,582,728	06/2003	Platz, et al.			
		6,572,893	06/2003	Gordon, et al.			
		6,569,458	05/2003	Gombotz, et al.			
		6,569,406	05/2003	Stevenson, et al.			
		6,565,885	05/2003	Tarara, et al.			
		6,565,871	05/2003	Roser, et al.			
		6,518,239	02/2003	Kuo, et al.			
		6,514,496	02/2003	Platz, et al.			
		6,509,006	01/2003	Platz, et al.			
		6,503,411	01/2003	Franks, et al.			
		6,479,049	11/2002	Platz, et al.			
		6,468,782	10/2002	Tunnacliffe, et al.			
		6,426,210	07/2002	Franks, et al.			
<i>SSL</i>		6,423,344	07/2002	Platz, et al.			

Examiner: <i>Julie L. Landau</i>	Date Considered: <i>11/27/07</i>
----------------------------------	----------------------------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
Information Disclosure Statement By Applicant		Applicant:	
<u>Page 2 of 23</u> (Use Several Sheets if Necessary)		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
U.S. Patent Documents			

SG L		6,423,334	07/2002	Brayden, et al.			
		6,416,739	07/2002	Rogerson, et al.			
		6,372,258	04/2002	Platz, et al.			
		6,365,190	04/2002	Gordon, et al.			
		6,358,530	03/2002	Eljamal, et al.			
		6,334,182	02/2002	Sutton, et al.			
		6,331,310	12/2001	Roser, et al.			
		6,313,102	11/2001	Colaco, et al.			
		6,309,671	10/2001	Foster, et al.			
		6,309,623	10/2001	Weers, et al.			
		6,303,582	10/2001	Eljamal, et al.			
		6,303,581	10/2001	Pearlman			
		6,290,991	09/2001	Roser, et al.			
		6,284,282	09/2001	Maa, et al.			
		6,258,341	07/2001	Foster, et al.			
		6,231,851	05/2001	Platz, et al.			
		6,207,135	03/2001	Rossling, et al.			
		6,190,859	02/2001	Putnak, et al.			
		6,187,344	02/2001	Eljamal, et al.			
		6,165,463	10/2000	Platz, et al			
		6,142,216	11/2000	Lannes			
		6,138,668	10/2000	Patton, et al.			
		6,136346	10/2000	Eljamal, et al.			
		6,123,936	09/2000	Platz, et al.			
		6,123,924	09/2000	Mistry, et al.			
		6,116,237	09/2000	Schultz, et al.			
		6,077,543	06/2000	Gordon, et al.			
		6,071,428	06/2000	Franks, et al.			
		6,060,069	05/2000	Hill, et al.			
		6,051,256	04/2000	Platz, et al.			
		6,034,080	03/2000	Colaco, et al.			
		6,013,638	01/2000	Crystal, et al.			
SG L		5,997,848	12/1999	Patton			

Examiner:	Date Considered
<u>See st. Landau</u>	<u>10/27/07</u>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		Applicant:	
<i>Page 3 of 23</i> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
U.S. Patent Documents			

<i>SL</i>	5,994,314	11/1999	Eljamal, et al.		
	5,993,805	11/1999	Sutton, et al.		
	5,993,783	11/1999	Eljamal, et al.		
	5,976,436	11/1999	Livesley, et al.		
	5,972,366	10/1999	Haynes, et al.		
	5,955,448	09/1999	Colaco, et al.		
	5,948,411	09/1999	Koyama, et al.		
	5,928,469	07/1999	Franks, et al.		
	5,891,873	04/1999	Colaco, et al.		
	5,851,453	12/1998	Hanna, et al.		
	5,849,700	12/1998	Sorenson, et al.		
	5,780,295	07/1998	Livesey, et al.		
	5,780,014	07/1998	Eljamal, et al.		
	5,775,320	07/1998	Patton, et al.		
	5,755,218	05/1998	Johansson, et al.		
	5,766,520	06/1998	Bronshtein		
	5,733,555	03/1998	Chu		
	5,728,574	03/1998	Legg		
	5,705,482	01/1998	Christensen, et al.		
	5,681,746	10/1997	Bodner, et al.		
	5,659,297	08/1997	Bernstein, et al.		
	5,655,521	08/1997	Faithful, et al.		
	5,654,278	08/1997	Sorenson		
	5,648,095	07/1997	Illum, et al.		
	5,642,728	07/1997	Andersson, et al.		
	5,631,225	05/1997	Sorenson		
	5,621,094	04/1997	Roser, et al.		
	5,607,915	03/1997	Patton, et al.		
	5,591,453	01/1997	Ducheyne, et al.		
	5,589,167	12/1996	Cleland, et al.		
	5,580,859	12/1996	Felgner, et al.		
	5,571,499	11/1996	Hafler, et al.		
<i>SL</i>	5,567,439	10/1996	Mters, et al.		

Examiner:	Date Considered
<i>Judith L. Landau</i>	<i>10/27/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b>	
<i>Page 4 of 23</i> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
U.S. Patent Documents			

<i>SAV</i>	5,547,696	08/1996	Sorenson			
	5,540,225	07/1996	Schutt			
	5,512,547	04/1996	Johnson, et al.			
	5,482,927	01/1996	Maniar, et al.			
	5,458,135	10/1995	Patton, et al.			
	5,453,514	09/1995	Niigata, et al.			
	5,425,951	06/1995	Goodrich, Jr., et al.			
	5,422,384	06/1995	Samuels, et al.			
	5,422,360	06/1995	Miyajima, et al.			
	5,404,871	04/1995	Goodman, et al.			
	5,403,861	04/1995	Goldwin, et al.			
	5,387,431	02/1995	Fuisz			
	5,384,345	01/1995	Naton, Paul E.			
	5,380,519	01/1995	Scheider, et al.			
	5,380,473	01/1995	Bogue, et al.			
	5,366,734	11/1994	Hutchinson			
	5,354,934	10/1994	Pitt, et al.			
	5,354,562	10/1994	Platz, et al.			
	5,348,852	09/1994	Bonderman			
	5,342,625	08/1994	Hauer, et al.			
	5,309,900	05/1994	Knoch, et al.			
	5,312,909	05/1994	Driessen, et al.			
	5,312,335	05/1994	McKinnon, et al.			
	5,306,506	04/1994	Zema, et al.			
	5,290,765	03/1994	Wettlaufer			
	5,270,048	12/1993	Drake			
	5,240,846	08/1993	Collins, et al.			
	5,240,843	08/1993	Gibson, et al.			
	5,240,712	08/1993	Smith, et al.			
	5,239,993	08/1993	Evans			
	5,215,079	06/1993	Fine, et al.			
	5,204,108	04/1993	Illum			
<i>SAV</i>	5,202,333	04/1993	Berger, et al.			

Examiner:	Date Considered
<i>Jill de Landrau</i>	<i>10/27/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
Information Disclosure Statement By Applicant		Applicant:	
<i>Page 5 of 23</i> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
U.S. Patent Documents			

<i>SOL</i>	5,202,159	04/1996	Chen, et al.			
	5,200,399	04/1993	Wettlaufer, et al.			
	5,160,745	11/1992	De Luca, et al.			
	5,149,653	09/1992	Roser			
	5,112,598	05/1992	Bielsalski			
	5,112,596	05/1992	Malfray-Camine			
	5,098,893	03/1992	Franks, et al.			
	5,089,181	02/1992	Hauser			
	5,049,389	09/1991	Radhakrishnan			
	5,049,388	09/1991	Knight, et al.			
	5,043,165	08/1991	Radhakrishnan			
	5,033,463	07/1991	Cocozza			
	5,026,772	06/1991	Kobayashi, et al.			
	5,026,566	06/1991	Roser			
	5,017,372	05/1991	Hastings			
	5,013,557	05/1991	Tai			
	4,999,384	04/1991	Roberts, et al.			
/	4,995,385	02/1991	Velentini, et al.			
	4,988,683	01/1991	Corbiere			
	4,984,158	01/1991	Hillsman			
	4,971,787	11/1990	Cherukurki, et al.			
	4,952,402	08/1990	Sparks, et al.			
	4,942,544	07/1990	McIntosh, et al.			
	4,907,583	03/1990	Wetterlin, et al.			
	4,906,463	03/1990	Cleary, et al.			
	4,891,319	01/1990	Roser			
	4,883,762	11/1989	Hoskins			
	4,866,051	09/1989	Hunt			
	4,865,871	09/1989	Livesey, et al.			
	4,861,627	08/1989	Mathiowitz, et al.			
	4,855,326	08/1989	Fuisz			
	4,847,079	07/1989	Kwan			
<i>SOL</i>	4,830,858	05/1989	Payne, et al.			

Examiner:	Date Considered
<i>J. L. d. standard</i>	<i>10/27/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
Information Disclosure Statement By Applicant		Applicant:	
<u>Page 6 of 23</u> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
U.S. Patent Documents			

<i>Stal</i>	4,824,938	04/1989	Koyama, et al.			
	4,819,629	04/1989	Jonson			
	4,814,436	03/1989	Shibata, et al.			
	4,812,444	03/1989	Mitsuhashi, et al.			
	4,793,997	12/1988	Drake, et al.			
	4,790,824	12/1988	Morrow, et al.			
	4,762,857	08/1988	Bollin, Jr., et al.			
	4,761,400	08/1988	Doat, et al.			
	4,758,583	07/1988	Cerami, et al.			
	4,739,754	04/1988	Shaner			
	4,721,709	01/1988	Seth, et al.			
	4,713,249	12/1987	Schröder			
	4,701,417	10/1987	Portenhauser, et al.			
	4,684,719	08/1987	Nishikawa, et al.			
	4,680,027	07/1987	Parsons, et al.			
	4,659,696	04/1987	Hirai, et al.			
	4,620,847	11/1986	Shishov, et al.			
	4,617,272	10/1986	Kirkwood, et al.			
	4,613,500	09/1986	Suzuki, et al.			
	4,591,552	05/1986	Neurath			
	4,588,744	05/1986	McHugh			
	4,534,343	08/1985	Nowacki, et al.			
	4,484,577	11/1984	Sackner, et al.			
	4,452,239	06/1984	Malem			
	4,407,786	10/1983	Drake, et al.			
	4,371,557	02/1983	Oppy, et al.			
	4,327,077	04/1982	Puglia, et al.			
	4,327,076	04/1982	Puglia, et al.			
	4,326,524	04/1982	Drake, Jr., et al.			
	4,253,468	03/1981	Lehmbeck			
	4,244,949	01/1981	Gupta			
	4,211,769	07/1980	Okada, et al.			
<i>Stal</i>	4,180,593	12/1979	Cohan			

Examiner:	<i>Saul J. Landau</i>	Date Considered	<i>10/27/07</i>
-----------	-----------------------	-----------------	-----------------

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>	<b>Atty. Docket No.:</b> 0054.10	<b>Application No.:</b> 09/886,296
<b>Information Disclosure Statement By Applicant</b>	<b>Applicant:</b> Tarara, et al.	
<u>Page 7 of 23</u> <i>(Use Several Sheets if Necessary)</i>	<b>Filing Date:</b> June 21, 2001	<b>Group:</b> 1616

Examiner: Judith L. Standard Date Considered 10/27/07

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b>	
<i>Page 8 of 23</i> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Foreign Patent or Published Foreign Patent Application</b>			

*References  
not submitted*

	902257	08/1985	BE					
	84-03520	06/1984	ES					
	0714905	06/1996	Europe					
	0616524	09/1994	Europe					
	0600730	08/1994	Europe					
	0520748	10/1992	Europe					
	0474874	03/1992	Europe					
	0463653	01/1992	Europe					
	0433679	06/1991	Europe					
	0430045	06/1991	Europe					
	0415567	09/1991	Europe					
	0383569	08/1990	Europe					
	0366303	05/1990	Europe					
	0360340	03/1990	Europe					
	0356154	02/1990	Europe					
	0325936	08/1989	Europe					
	0282179	09/1888	Europe					
	0257956	03/1998	Europe					
	0229810	07/1987	Europe					
	0222313	05/1987	Europe					
	0140489	05/1985	Europe					
	0139286	05/1985	Europe					
	0136030	04/1985	Europe					
	0111216	06/1984	Europe					
	0090356	10/1983	Europe					
	0072046	02/1983	Europe					
	0015123	03/1980	Europe					
	161072	10/1904	DE					
	471490	08/1931	DE					
	1080265	04/1960	DE					
	3141498	04/1983	DE					
	2238476	02/1975	FR					
	1288094	09/1972	GB					
	1381588	01/1975	GB					
	1477775	06/1977	GB					
	1533012	11/1978	GB					
	2126588	03/1984	GB					
	21878191	01/1987	GB					

Examiner:	Date Considered
<i>D. L. Landau</i>	<i>10/27/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b>	
<i>Page 9 of 23</i> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Foreign Patent or Published Foreign Patent Application</b>			

	06-100464	04/1994	JP					
	52-139789	11/1977	JP					
	58-216695	12/1983	JP					
	59-095885	06/1984	JP					
	60-244288	12/1985	JP					
	62-228272	10/1987	JP					
	62-255434	11/1987	JP					
	01/95874	12/2001	WO					
	01/87278	11/2001	WO					
	01/00263	01/2001	WO					
	00/72904	12/2000	WO					
	00/21594	04/2000	WO					
	00/10541	03/2000	WO					
	99/66903	12/1999	WO					
	99/38493	08/1999	WO					
	99/32098	07/1999	WO					
	98/58989	12/1998	WO					
	98/24882	06/1998	WO					
	97/34689	09/1997	WO					
	96/40077	12/1996	WO					
	96/40049	12/1996	WO					
	96/32096	10/1996	WO					
	96/27393	09/0996	WO					
	96/11745	06/1996	WO					
	96/09085	03/1996	WO					
	96/03978	02/1996	WO					
	95/33488	12/1995	WO					
	95/31479	11/1995	WO					
	95/24183	09/1995	WO					
	95/20979	08/1995	WO					
	95/06126	03/1995	WO					
	95/01324	01/1995	WO					
	95/00127	01/1995	WO					
	94/24263	10/1994	WO					
	94/22423	10/1994	WO					
	94/13271	06/1994	WO					
	94/08552	04/1994	WO					
	94/07514	04/1994	WO					
	93/23110	11/1993	WO					

Examiner:	Date Considered
<i>Dal A. Landa</i>	<i>10/27/02</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>	<b>Atty. Docket No.:</b> 0054.10	<b>Application No.:</b> 09/886,296
<b>Information Disclosure Statement By Applicant</b>  <i>Page 10 of 23</i> <i>(Use Several Sheets if Necessary)</i>	<b>Applicant:</b> Tarara, et al.	
	<b>Filing Date:</b> June 21, 2001	<b>Group:</b> 1616
<b>Foreign Patent or Published Foreign Patent Application</b>		

References  
not  
submitted

Examiner:	<u>Paul A. Dandane</u>	Date Considered
		10/27/07

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b>	
<u><i>Page 11 of 23</i></u> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		<b>Filing Date:</b>	<b>Group:</b>
		June 21, 2001	1616
<b>Other Documents</b>			

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
		Advertisement for "Stop 'n Grow" manufactured by The Mentholatum Co. Ltd., East Kilbride, Scotland G74 5P3. <b>DATE MISSING</b>
<i>SL</i>		Agrimi, U., et al. "Amyloid, Amyloid-Inducers, Cytokines and Heavy Metals in Scrapie and Other Human and Animal Subacute Spongiform Encephalopathies: Some Hypotheses", <i>Med. Hypotheses</i> , 40(2): 113-116 (1993).
<i>SL</i>		Akers, M.J., et al., "Glycine Crystallization During Freezing: The Effects of Salt Form, pH, and Ionic Strength", <i>Pharmaceutical Research</i> 12(10):1457-1461 (1995).
<i>SL</i>		Akoh, et al., "One-stage synthesis of raffinose fatty acid polyesters", <i>J. Food Sci.</i> , 52:1570-1576 (1987).
<i>SL</i>		Alberts, B., et al., <u>Molecular Biology of the Cell</u> , 2 <sup>nd</sup> ed., Garland Publishing, Inc., Ch. 2, page 58 (1989).
<i>SL</i>		Aldous, et al., "The Crystallization of Hydrates from Amorphous Carbohydrates", <i>Cryo-Letters</i> , 16:181-186 (1995).
<i>SL</i>		Allen, D.J., et al. "Determination of the Degree of Crystallinity in Solid-Solid Equilibria", <i>J. Pharm. Sci.</i> , 58:1190-1193 (1969).
<i>SL</i>		Allison, S.D., et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", <i>Journal of Pharmaceutical Sciences</i> 89(5): 682-691 (2000).
<i>SL</i>		Allison, S.D. and Anchordoquy, Thomas J., <i>Lyophilization of Nonviral Gene Delivery Systems, METHODS IN MOLECULAR MEDICINE, NONVIRAL VECTORS FOR GENE THERAPY</i> , Ch. 18, p 225-252 (Mark A. Findeis ed., Humana Press, 2001).
<i>SL</i>		Amidon, G.E., et al., "Powder Flow Testing in Preformulation and Formulation Development", <i>Pharm. Manuf.</i> , 2: 20-31 (1985).
<i>SL</i>		Anchordoquy, Thomas J., Physical Stabilization of DNA Based Therapeutics, 6(9): DDT 463-470 (May 2001).
<i>SL</i>		Anekwe, J., et al., "Relaxation Constants as a Predictor of Protein Stabilization", <i>Biocalorimetry: Applications of Calorimetry in the Biological Science</i> , J.E. Ladbury and B.Z. Chowdhry, editors, John Wiley & Sons, pp. 243-251 (1998).
<i>SL</i>		"Drug Absorption and Availability", <i>Modern Pharmaceutics</i> , 3 <sup>rd</sup> edition, G.S. Banker, et al. (eds), Marcel Dekker, Inc., pp. 145 (1996).
<i>SL</i>		Bandara, G., et al., "Interarticular Expression of Biologically Active Interleukin 1-Receptor-Antagonist Protein by Ex Vivo Gene Transfer", <i>Proc. Natl. Acad. Sci.</i> , 90:10764-10768 (November 1993).
<i>SL</i>		Bell, J.H., et al., "Dry Powder Aerosols I: A New Powder Inhalation Device", <i>J. Pharm. Sci.</i> , 60(10): 1559-1564 (October 1971).

Examiner:	Date Considered
<i>SL - sl. clarke</i>	<i>10/27/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		Applicant:	
<u>Page 12 of 23</u> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Other Documents</b>			

<i>gal</i>	Belopol'skaya, T.V., et al., "The Effect of Water as Natural Plasticizer on Thermal Properties of Denatured DNA Studied by Calorimetry 4 VESTNIK SANKT-PETERSBURGSKOGO UNIVERSITETA SERIYA, pp. 16-22, abstract only, 2 pgs. (1999).
<i>gal</i>	Ben-Jenria, Abdellaziz, et al., "Large Powous Particles for Sustained Protection from Carbochol-Induced Bronchoconstriction in Guinea Pigs", <i>Pharma. Res.</i> , Vol. 16, No. 4, p. 555-561.
<i>gal</i>	Bigsbee, et al. "Solid State Liability of Insulin: Comparison of Crystalline and Amorphous Forms", <i>Pharmaceutical Research</i> 10(10): Abstract No. PDD 7418, page S-279 (1993).
<i>gal</i>	Blakeley, et al., "Dry instant blood typing for bedside use", <i>Lancet</i> , 336: 854-855 (1990).
<i>gal</i>	Bootsma, H.P.R., et al., " $\beta$ -Cyclodextrin as an Excipient in Solid Oral Dosage Forms: In Vitro and In Vivo Evaluation of Spray-Dried Diazepan- $\beta$ -Cyclodextrin Products", <i>International Journal of Pharmaceutics</i> 51:213-223 (1989).
<i>gal</i>	Borgstrom, et al., "Lung Deposition of Budesonide Inhaled via Turbuhaler", <i>Eur. Respir. J.</i> , p. 69-73 (February 26, 1994).
<i>gal</i>	Branchu, S., et al., "The Effect of Cyclodestrins on Monomeric Protein Unfolding", <i>Biocalorimetry: Applications of Calorimetry in the Biological Sciences</i> , J.E. Ladbury and B.Z. Chowdhry (eds.), John Wiley & Sons, Ltd., 297-301 (1998).
<i>gal</i>	Branchu, S., et al., "Hydroxypropyl- $\beta$ -Cyclodextrin Inhibits Spray-Drying-Induced Inactivation of $\beta$ -Galactosidase", <i>Journal of Pharmaceutical Sciences</i> 88(9): 905-911 (1999).
<i>gal</i>	Brange, et al., "Chemical Stability of Insulin. I. Hydrolytic Degradation During Storage of Pharmaceutical Preparations", <i>Pharmaceutical Research</i> 9(6): 715-726 (1992).
<i>gal</i>	Broadhead, J., et al., The Effect of Process and Formulation Variable on the Properties of Spray-Drive $\beta$ -Galactosidase", <i>J. Pharm. Pharmacol.</i> 46(6): 458-567 (June 1994).
<i>gal</i>	Broadhead, J., et al., "The Spray Drying of Pharmaceuticals, 18 Drug Development and Industrial Pharmacy, p. 1169-1206 (1992).
<i>gal</i>	Brown, "A Therapeutic Panorama of the Spongiform Encephalopathies", <i>Antiviral Chem. Chemother.</i> 1(2): 75-83 (1990).
<i>gal</i>	Buitink, Julia, et al., <i>High Critical Temperature above Tg May Contribute to the Stability of Biological Systems</i> , 79 BIOPHYSICAL JOURNAL, 1119-1128 (August 2000).
<i>gal</i>	Burvall, et al., "Storage of Lactose-Hydrolysed Dried Milk: Effect of Water Activity on the Protein Nutritional Value", <i>Journal of Dairy Research</i> 45: 381-389 (1978).
<i>gal</i>	Byron, Peter R., et al., <i>Drug Carrier Selection – Important Physicochemical Characteristics RESPIRATORY DRUG DELIVERY</i> , 5 <sup>th</sup> Ed., Interpharm Press., 103-113 (1996).
<i>gal</i>	Byström, et al., "Microcalorimetry – A Novel Technique for Characterization of Powders", <i>Respiratory Drug Delivery IV</i> , p. 297-302 (1994).

Examiner:	Date Considered
	<i>10/27/02</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0054.10	<b>Application No.:</b> 09/886,296
<b>Information Disclosure Statement By Applicant</b> <i>Page 13 of 23</i> (Use Several Sheets if Necessary)		<b>Applicant:</b> Tarara, et al.	
		<b>Filing Date:</b> June 21, 2001	<b>Group:</b> 1616
<b>Other Documents</b>			

<i>SAV</i>	Carpenter, John F., et al., "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice", <i>Pharmaceutical Res.</i> , 14(8): 969-975 (1997).
<i>SAV</i>	Caughey, et al., "Sulphated Polyanion Inhibition of Scrapie-Associated PrP Accumulation in Cultured Cells", <i>J. Virol.</i> , 67(2): 643-650 (1993).
<i>SAV</i>	Chan, et al., "Formulation of Vaccine Adjuvant Muramylpeptides (MDP). 1. Characterization of Amorphous and Crystalline Forms of a Muramylpeptide Analogue", <i>Pharmaceutical Research</i> , 5(8): 523-527 (1988).
<i>SAV</i>	Chan, Hak-Kim, et al., "Solid State Characterization of Spray-Dried Powders of Recombinant Human Deoxyribonuclease (RhDNase)", <i>Journal of Pharmaceutical Sciences</i> , 87(5): 647-654 (1998).
<i>SAV</i>	Chavan, V., et al., "Effect of Rise in Simulated Inspiratory Flow Rate and Carrier Particle Size on Powder Emptying From Dry Powder Inhalers", <i>AAPS PharmSci 2000</i> , 2(2) article 10 [on-line] Retrieved from the Internet <URL: <a href="http://www.pharmsci.org">http://www.pharmsci.org</a> > 7 pages (2000).
<i>SAV</i>	Chavan, V., et al., Effect of Particle Size and Rise in Simulated Inspiratory Flow Rate on Device Emptying in a Dry Powder Inhaler SYstem", [on-line] [retrieved 01/07/2005] Retrieved from the Internet <URL: <a href="http://www.aapspharmsci.org/abstracts/AM_1999/1001.htm">http://www.aapspharmsci.org/abstracts/AM_1999/1001.htm</a> > 1 page (1999).
<i>SAV</i>	Chawla, et al., "Production of Spray Dried Salbutamol Sulphate for Use in Dry Powder Aerosol Formulation", <i>International Journal of Pharmaceutics</i> , 108: 233-240 (1994).
<i>SAV</i>	Chiou, et al., "Pharmaceutical Applications of Solid Dispersion Systems", <i>J. Pharm.</i> , 60(9): 1281-1302 (1971).
<i>SAV</i>	Cleland, et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation and Oxidation", <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 10(4): 307-377 (1993).
<i>SAV</i>	Colaco, et al., "Extraordinary Stability of Enzymes Dried in Trehalose: Simplified Molecular Biology", <i>Bio/Technology</i> 10: 1007-1011 (1992).
<i>SAV</i>	Colaco, et al., "Trehalose Stabilization of Biological Molecules", <i>Biotechnol. Internet.</i> , pp. 345, 347-350 (1992).
<i>SAV</i>	Colaco, et al., "Chapter 14: Chemistry of Protein Stabilization by Trehalose", <i>ACS Symposium Series 567, Formulation and Delivery of Proteins and Peptides</i> , J.L. Cleland & R. Langer, pp. 222-240 (1994).
<i>SAV</i>	Constantino, et al., "Moisture-Induced Aggregation of Lyophilized Insulin", <i>Pharmaceutical Research</i> , 11(1): 21-29 (1994).
<i>SAV</i>	Constantino, H.R., et al., "Effect of Mannitol Crystallization on the Stability and Aerosol Performance of a Spray-Dried Pharmaceutical Protein, Recombinant Humanized Anti-IgE Monoclonal Antibody", <i>Journal of Pharmaceutical Sciences</i> , 87(11): 1406-1411 (1998).
<i>SAV</i>	Craig, I.D., et al., "Maillard Reaction Kinetics in Model Preservation Systems in the Vicinity of the Glass Transition: Experiment and Theory", <i>J. Agric. Food Chem.</i> 49(10): 4706-4712 (2001).

<b>Examiner:</b> <i>Sav d. lardare</i>	<b>Date Considered:</b> <i>10/27/07</i>
---	--

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		Applicant:	
<u>Page 14 of 23</u> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Other Documents</b>			

<i>CJL</i>	Crommelin, et al., "Liposomes", Chapter 3, <i>Colloidal Drug Delivery Systems</i> , J. Kreuter, editor: 73-190 (1994).
<i>CJL</i>	Crowe, et al., "Are Freezing and Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes with Biomolecules", <i>Cryobiol.</i> 27: 219-231 (1990).
<i>CJL</i>	Crowe, et al., "Interactions of Sugars with Membranes", <i>Biochimica et Biophysica Acta</i> , 947: 367-384 (1988).
<i>CJL</i>	Crowe, John H., et al., "The Role of Vitrification in Anhydrobiosis", <i>Annu. Rev. Physiol.</i> , 60: 73-103 (1998).
<i>CJL</i>	Crowe, Lois M., et al., "Is Trehalose Special for Preserving Dry Biomaterials?", <i>Biophysical Journal</i> , 71: 2087-2093 (1996).
<i>CJL</i>	D'Hondt, "Possible Approaches to Develop Vaccines Against Hepatitis A", <i>Vaccine</i> 10 (Supplement 1): S48-S52 (1992).
<i>CJL</i>	Daemen, et al., "The Destruction of Enzymes and Bacteria During the Spray-Drying of Milk and Whey, 2. The Effect of the Drying Conditions", <i>Neth. Milk Dairy J.</i> , 36: 211-229 (1982).
<i>CJL</i>	Dalby, R.N., et al., "Droplets Drying and Electrostatic Collection a Novel Alternative to Conventional Comminution Techniques", <i>Journal of Biopharmaceutical Sciences</i> 3 (1/2): 091-099 (1992).
<i>CJL</i>	Dalby, et al., "Relationship Between Particles Morphology and Drug Release Properties After Hydration of Aerosols Properties Containing Liposome Forming Ingredients", <i>Pharmaceutical Research</i> , 5(10): S-94, Abstract PD 888 (1988).
<i>CJL</i>	Darrington, et al., "Evidence for a Common Intermediate in Insulin Deamidation and Covalent Dimer Formation: Effects of pH and Aniline Trapping in Dilute Acidic Solutions", <i>Journal of Pharmaceutical Sciences</i> , 84(3): 275-282 (1995).
<i>CJL</i>	DeCarlo, S., et al., "Unexpected Property of Trehakose as Observed by Cyro-Electron Microscopy", <i>Journal of Microscopy</i> , 196(1): 40-45 (1995).
<i>CJL</i>	DeYoung, "The AeroDose Multidose Inhaler Device Design and Delivery Characteristics", <i>Respiratory Drug Delivery VI</i> , p. 91 (1998).
<i>CJL</i>	Dose, et al., "Survival in Extreme Dryness and DNA-Single-Strand Breaks", <i>Advances in Space Research</i> , 12(4)221-229 (1992).
<i>CJL</i>	Dunbar, et al., "Dispersion and Characterization of Pharmaceutical Dry Powder Aerosols", <i>KONA</i> (February 26, 2998).
<i>CJL</i>	During, M.J., et al., "Long-Term Behavioral Recovery in Parkinsonian Rats by an HSV Vector Expressing Tyrosine Hydrosylase", <i>Science</i> , 266(5189): 856-857 (November 1994).
<i>CJL</i>	Edwards, A.D., et al., "Crystallization of Pure Anhydrous Polymorphs of Carbamazepine by Solution Enhanced Dispersion with Supercritical Fluids (SEDS™)", <i>Journal of Pharmaceutical Sciences</i> , 90(8): 1115-1124 (2001).
<i>CJL</i>	Edwards, et al., "Large Porous Particles for Pulmonary Drug Delivery", <i>Science</i> , Vol. 276, pp. 1868-1871 (June 1997).

Examiner:	Date Considered
<i>Paul A. Landau</i>	<i>10/27/03</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b>	
<u>Page 15 of 23</u> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Other Documents</b>			

<i>C&amp;L</i>	/	Eleutherio, et al., "Role of the Trehalose Carrier in Dehydration Resistance of <i>Saccharomyces Cerevisiae</i> ", <i>Biochimica et Biophysica Acta</i> , 1156: 263-266 (1993).
	/	Fahy, et al., "Vitrification as an Approach to Cryopreservation", <i>Cryobiology</i> , 21: 407-426 (1984).
	/	Finar, I.L., "§14. Trehalose, m.p. 203°C", under "Carbohydrate" Organic Chemistry, Vol. 2, Stereochemistry and the Chemistry of Natural Products, 5 <sup>th</sup> edition, Longman, page. 323 (1996).
	/	Forbes, R.T., et al., "Water Vapor Sorption Studies on the Physical Stability of a Series of Spray-Dried Protein/Sugar Powders for Inhalation", <i>Journal of Pharmaceutical Sciences</i> , 87(11): 1316-1321 (1998).
	/	Franks, "Freeze Drying: From Empiricism to Predictability", <i>Cryo-Letters</i> , 11: 93-110 (1990).
	/	Franks, "Materials Science and the Production of Shelf-Stable Biologicals", <i>Pharmaceutical Technological International</i> , 24: 24-34 (October 1991).
	/	Franks, "Separation, Improved Freeze-Drying, an Analysis of the Basic Scientific Principles", <i>Process Biochemistry</i> , 24(1): iii-vii (1989).
	/	Franks, "Accelerated Stability Testing of Bioproducts: Attractions and Pitfalls", <i>TIBTECH</i> , 12: 114-117 (1994).
	/	French, Donna L., et al., "The Influence of Formulation on Emission, Deaggregation and Deposition of Dry Powders for Inhalation," <i>J. Aerosol Science</i> , Vol. 27, No. 5, pp. 769-783 (1996).
	/	"Chapter 89—Oral Solid Dosage Forms, "In <i>Remington's Pharmaceutical Sciences</i> , 18 <sup>th</sup> Edition, Mack Publishing Co., Gennaro, A.R., pp. 1646-1647.
	/	Gonda, et al., "Characterization of Hygroscopic Inhalation Aerosols", In: <i>Particle Size Analysis</i> , (Eds. N.G. Stanley-Wood and T. Allen, Wiley Heyden Ltd., NY), pp. 31-43 (1981).
	/	Green, et al., "The Protein-Glass Analogy: Some Insights from Homopeptide Comparisons", <i>J. Phys. Chem.</i> , 98: 13780-13790 (April 1994).
	/	Green, et al., "Phase Relations and Vitrification in Saccharide-Water Solutions and the Trehalose Anomaly", <i>J. Phys. Chem.</i> , 93: 2880-2882 (1989).
	/	Hahn, et al., "Solid Surfactant Solutions of Active Ingredients in Sugar Esters", <i>Pharmaceutical Research</i> , 6: 958-959 (1989).
	/	Hancock, et al., "The Use of Solution Theories for Predicting Water Vapor Absorption by Amorphous Pharmaceutical Solids: A Test of the Flory-Huggins and Vrentas Models", <i>Pharmaceutical Research</i> , 10(9): 1262-1267 (1993).
	/	Hancock, et al., "Molecular Mobility of Amorphous Pharmaceutical Solids Below Their Glass Transition Temperatures", <i>Pharmaceutical Research</i> , 12(6): 799-806 (1995).
<i>SLR</i>	/	Hancock, B.C., et al., "The Effect of Temperature on Water Vapor Sorption by Some Amorphous Pharmaceutical Sugars", <i>Pharmaceutical Development and Technology</i> , 4(1): 125-131 (1999).

Examiner	Date Considered
<i>D. Linda</i>	<i>10/27/01</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		Applicant:	
<i>Page 16 of 23</i> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Other Documents</b>			

<i>SOL</i>	Hancock, B.C., et al., "The Relationship Between the Glass Transition Temperature and Water Content of Amorphous Pharmaceutical Solids", <i>Pharmaceutical Research</i> , 11(4): 471-477 (1994).
<i>SOL</i>	Hancock, et al., "A Pragmatic Test of Simple Calorimetric Method for Determining the Fragility of some Amorphous Pharmaceutical Materials", <i>Pharm. Res.</i> , 15(5): 762-767 (1998).
<i>SOL</i>	Hanes, et al., "Porous Dry-Powder PLGA Microspheres coated with Lung Surfactant for Systematic Insulin Delivery via the Lung", <i>Proc. Int'l. Symp. Control Rel. Bioactive Matter</i> , 24: 57-58 (1997).
<i>SOL</i>	Harwood, C.F., "Compaction Effect on Flow Property Indexes for Powders", <i>J. Pharm. Sci.</i> , 60:161-163 (1971).
<i>SOL</i>	Hatley, R.H.M., et al., "Stabilization of Labile Materials by Amorphous Carbohydrates Glass Fragility and the Physiochemical Properties that make Trehalose a Superior Excipient", <i>Pharmaceutical Research</i> , 13(9 Suppl.) PDD 7165: S274 (1996).
<i>SOL</i>	"Pfizer and Inhale Therapeutic Systems Enter Pulmonary Insulin Collaboration for Dry Powder Aerosol Delivery", <i>Health News Daily</i> , Vol. 7, No. 13, pp. 4-5 (January 1995).
<i>SOL</i>	Heitefuss, R., et al., "The Stabilization of Extracts of Cabbage Leaf Proteins by Polyhydroxy Compounds for Electrophoretic and Immunological Studies", <i>Archives of Biochemistry and Biophysics</i> , 85: 200-208 (1959).
<i>SOL</i>	Heller, Martin C., et al., "Protein Formulation and Lyophilization Cycle Design: Prevention of Damage Due to Freeze-Concentration Induced Phase Separation 63 BIOTECHNOLOGY & BIOENGINEERING, 166-174 (1999).
<i>SOL</i>	Herrington, T.M., et al., "Physico-Chemical Studies on Sugar Glasses. I. Rates of Crystallization", <i>Journal of Food Technology</i> , 19: 409-425 (1984).
<i>SOL</i>	Hickey, A. J. et al., "Behavoir of Hygroscopic Pharmaceutical Aerosols and the Influence of Hydrophobic Additives," <i>Pharmaceutical Research</i> 10(1):1-7 (1993).
<i>SOL</i>	Hickey, A. J. et al., "Methods of Aerosol Particle Size Characterization," <i>Pharmaceutical Inhalation Aerosol Technology</i> 8:219-253 (1992). <i>Not Legible</i>
<i>SOL</i>	Hoener, Betty-Ann et al., "Factors Influencing Drug Absorption and Availability" <i>Modern Pharmaceutics</i> , Gilber S. Banker et al., eds., Marcel Dekker Inc., Chapter 4, pp. 121-153 (1996).
<i>SOL</i>	Ibrahim, A. L. et al., "Sprah Vaccination With an Improved F Newcastle Disease Vaccine. A Comparison of Efficacy With the B1 and La Sota Vaccines," <i>Br. Vet. J.</i> 139:213-219 (1983).
<i>SOL</i>	Igaki, N. et al., "The Inhibition of the Maillard Reaction by L-Lysine In-Vitro," <i>J. Jpn. Diabetes Soc.</i> 34(5):403-407 (1991) including English abstract.
<i>SOL</i>	Iglesias et al., "Adsorption Isotherm of Amorphous Trehalos", <i>J. Sci. food Agric.</i> 75:183-186 (1997).
<i>SOL</i>	Jameel, F. et al., "Freeze Drying Properties of Some Oligonucleotides", <i>Pharmaceutical Development and Technology</i> 6(2):151-157 (2001).

Examiner:	Date Considered
<i>Dr. dd. Landau</i>	<i>10/27/04</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
Information Disclosure Statement By Applicant		Applicant:	
<u>Page 17 of 23</u> (Use Several Sheets if Necessary)		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
Other Documents			

<i>GJL</i>	/	Jovanovic-Peterson, L. et al., "Jet-injected insulin is associated with decreased antibody production and postprandial glucose variability when compared with needle injected insulin in gestational diabetic women," <i>Diabetes Care</i> 16(11):1479-1484 (November 1993).
	/	Kachura, "Method of Drying Lactic Acid Bacteria," Vinodelie I Vinogradarstvo SSSR 2:49-50, English Abstract only, one page (1985).
	/	Kanna, K. et al., "Denaturation of Fish Muscle Protein by Dehydration" <i>Bull. Tokai Reg. Fish. Res. Lab.</i> 77:70-76 English abstract (1974).
	/	Karmas, R. et al., "Effect of Glass Transition on Rates of Nonenzymatic Browning in Food Systems," <i>J. Agric. Food Chem.</i> 40:873-879 (1992).
	/	Khan, R. "Chemistry And New Uses Of Sucrose: How Important?" <i>Pure &amp; Appl. Chem.</i> 56(7):833-844 (1984).
	/	Khan, R. "Cyclic Acetals Of 4,1',6'-Tricholoro-4,1',6'-Trideoxy-Galacto-Sucrose And Their Conversion Into Methyl Ether Derivatives," <i>Carb. Res.</i> 198:275-283 (1990).
	/	Klein, T. M. et al., "High Velocity Microprojectiles For Delivering Nucleic Acids Into Living Cells," <i>Nature</i> 327:70-73 (1987).
	/	Labuza et al., "Glass Transition Temperatures of Food Systems", [on-line] [retrieved 09/2005] Retrieved from the Internet <URL: <a href="http://faculty.che.umn.edu/fscn/Ted">http://faculty.che.umn.edu/fscn/Ted</a> Lebuza/PDF files/Isotherm Folder/Tg%20compilation.pdf> pp. 1-31 (January 1992).
	/	Labruede, P. et al., "Protective Effect of Sucrose on Spray Drying of Ocxyhemoglobin," <i>Journal of Pharmaceutical Sciences</i> . 78(3):223-229 (1989).
	✓	Lai, M. C. et al., "Solid-State Chemical Stability of Proteins and Peptides", <i>Journal of Pharmaceutical Sciences</i> 88(5):489-500 (1999).
	/	Laube, B. L. et al., "Targeting Aerosol Deposition in Patients With Cystic Fibrosis, Effects of Alterations in Particle Size and Inspiratory Flow Rate", <i>Chest</i> 118(4): 1069-1076 (2000).
	/	Ledl, F., et al., "New Aspects of the Maillard Reaction in Foods and in the Human Body," <i>Ang. Chem. Int. Ed. Engl.</i> 29:565-594 (June 1990).
	/	Lee, C. K. <i>Developments in Food Carbohydrate - 2nd edition</i> Applied Science Publishers, London, Table of Contents, 4 pages (1980).
	/	Lehninger, Albert L. <i>The Molecular Basis of Cell Structure and Function BIOCHEMISTRY</i> , Chapter 31, 859-890 (Worth Publishers Inc., 2nd edition, 1975).
	/	Leslie, S. B. et al., "Trehalose and sucrose protect both membranes and proteins in intact bacteria during drying", <i>Appl. Env. Microbiol.</i> 61(10): 3592-3597 (1995).
	/	Leuner, C. et al., "Improving Drug Solubility for Oral Delivery Using Solid Dispersions", <i>European Journal of Pharmaceutics and Biopharmaceutics</i> 50:47-60 (2000).
	✓	Levine et al., "Another View of Trehalose for Drying and Stabilizing Biological Materials," <i>Biopharm</i> 5:36-40 (1992).
	/	Lin, S.-Y. et al., "Solid Particles of Drug-β-Cyclodextrin Inclusion Complexes Directly Prepared by a Spray-Drying Technique", <i>International Journal of Pharmaceutics</i> , 56:249-259 (1989).
<i>GJL</i>	/	Louis, P. et al., "Survival Of Escherichia Coli During Drying And Storage In The Presence of Compatible Solutes" <i>Appl. Microbiol. Biotechnol.</i> 41:684-688 (1994).

Examiner:	Date Considered
<i>Paul J. Landau</i>	10/21/07

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b> <i>Page 18 of 23</i> <i>(Use Several Sheets if Necessary)</i>		<b>Applicant:</b>	
		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Other Documents</b>			

<i>GIA V</i>	<input checked="" type="checkbox"/>	Lueckel, B. et al., "Effects of Formulation and Process Variables on the Aggregation of Freeze-Dried Interleukin-6 (IL-6) After Lyophilization and on Storage", <i>Pharmaceutical Development and Technology</i> 3(3):337-346 (1998).	
		Masinde, Lwandiko E., et al., "Aerosolized Aqueous Suspension of Poly(L-lactic Acid) Microspheres.", <i>100 International Journal of Pharmaceutics</i> , pp. 123-131 (1993).	
	<input checked="" type="checkbox"/>	MacKenzie, "Collapse During Freeze Drying-Qualitative and Quantitative Aspects." <i>Freeze Drying and Advanced Food Technology</i> , edited by Goldblith, Rey and Rothmayr: 277-307 (1975).	
	<input checked="" type="checkbox"/>	Makower, B. et al., "Equilibrium Moisture Content and Crystallization of Amorphous Sucrose and Glucose," <i>Agric. And Food Chem.</i> 4(1):72-77 (1956).	
	<input checked="" type="checkbox"/>	Martin, A. et al., States of Matter and Phase Equilibria PHYSICAL PHARMACY, PHYSICAL CHEMICAL PRINCIPLES IN THE PHARMACEUTICAL SCIENCES, 3rd. ed., Chapter 4, 62-92 (1983).	
	<input checked="" type="checkbox"/>	Masters, K. <i>SPRAY DRYING HANDBOOK</i> , England; Longman Scientific & Technical, 5th ed., pp. 640-642 (1991).	
	<input checked="" type="checkbox"/>	Masters, K. <i>SPRAY DRYING HANDBOOK</i> , England; Longman Scientific & Technical and John Wiley & Sons, Inc., 5th ed., pp. 309-352 (1991).	
	<input checked="" type="checkbox"/>	Masters, K <i>SPRAY DRYING HANDBOOK</i> , 5th ed., Chapters 13 and 15, pp. 491-537 and 587-642 (1991).	
	<input checked="" type="checkbox"/>	Matsuda, Y. et al., "Amorphism and Physicochemical Stability of Spray Dried Frusemide," <i>J. Pharm. Pharmacol.</i> 44:627-633, received November 7, 1991 (1992).	
	<input checked="" type="checkbox"/>	Mattern et al., "Formulation of Proteins in Vacuum-Dried Glasses. II. Process and Storage Stability in Sugar-Free Amino Acid Systems", <i>Pharmaceutical Development &amp; Technology</i> 4(2):199-208 (1999).	
	<input checked="" type="checkbox"/>	Miller, D. P. et al., "Stabilization of Lactate Dehydrogenase Following Freeze Thawing and Vacuum-Drying in the Presence of Trehalose and Borate", <i>Pharmaceutical Research</i> 15(8):1215-1221(1998).	
	<input checked="" type="checkbox"/>	Monnier et al., <i>Mechanisms of Protection Against Damage Mediated by the Maillard Reaction in Aging Gerontology</i> 37:152-165 (1991).	
	<input checked="" type="checkbox"/>	Mouradian, R. et al., "Degradation of Functional Integrity During Long-Term. Storage of a Freeze-Dried Biological Membrane", <i>Cryobiology</i> 22: 119-127 (1985).	
	<input checked="" type="checkbox"/>	Moynihan et al., "Dependence of the Glass Transition Temperature on Heating and Cooling Rate", <i>J. Physical. Chem.</i> 78(26): 2673-2677 (1974).	
	<input checked="" type="checkbox"/>	Muller, et al., "On the Influence of Molecular Forces on the Deformation of an Elastic Sphere and It's Sticking to a Rigid Plane", <i>J. Colloid Interface Sci.</i> , 77: 91 (1980).	
	<input checked="" type="checkbox"/>	Mumenthaler, M. et al., "Feasibility Study on Spray-Drying Protein Pharmaceuticals: Recombinant Human Growth Hormone and Tissue-Type Plasminogen Activator," <i>Clinical Research</i> 11(I): 12-20 (1994).	
	<input checked="" type="checkbox"/>	Murphy, B. R. et al., "Chapter 19: Immunization Against Viruses", in <i>Fields of Virology</i> , 2nd Edition, Volume 1, Raven Press, pp. 469-502 (1990).	
<i>GIA V</i>	<input checked="" type="checkbox"/>	Murphy, Brian R. et al., <i>Fields Virology</i> , Volume 1, Chapter 16, <i>Immunization Against Virus Disease</i> , 467, at page 468, first full paragraph, first column; lines 26-33 (Bernard N. Fields et al. eds., Lippincott-Raven Publishers, 3rd ed. 1996).	

Examiner:	Date Considered
<i>Julie A. Landau</i>	<i>10/27/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		Applicant:	
<i>Page 19 of 23</i> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Other Documents</b>			

<i>CPL</i>	/	Mutterlein, et al., "New Technology for Generating Inhalation Aerosols—Preliminary Results with the Piezoelectrical Pocket-Inhaler", <i>J. Aerosol Med.</i> , 1: 231 (1988).
	/	Nabel, G. J. et al., "Direct Gene Transfer With DNA-Liposome Complexes in Melanoma," <i>Proc. Natl. Acad. Sci.</i> 90:11307-11311.
	.	Nabel, G. J. et al., "Immunotherapy of Malignancy by In Vivo Gene Transfer Into Tumors," <i>Hum. Gene. Ther.</i> 3(4): 3 99-4 10 (August 1992) Abstract only [on-line] [retrieved 112/21/04] Retrieved from the Internet < URL: <a href="http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&amp;db=pubmed&amp;dopt=Abstr">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&amp;db=pubmed&amp;dopt=Abstr</a>
	.	Naini, V. et al., "Particles for Inhalation Produced by Spray Drying and Electrostatic Precipitation of Different Protein-Sugar Solutions", <i>Respiratory Drug Delivery V</i> , pp. 382-384 (1996).
	.	Naini, V. et al., "Physicochemical Stability of Crystalline Sugars and Their Spray-Dried Forms: Dependence Upon Relative Humidity and Suitability for Use in Powder Inhalers", <i>Drug Development and Industrial Pharmacy</i> 24(10):895-909 (1998).
	.	Niven, R. W., "Delivery of Biotherapeutics by Inhalation Aerosol," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 12(2&3):151-231 (1995).
	.	Niven, R. W., "Delivery of Biotherapeutics by Inhalation Aerosols," <i>Pharmaceutical Technology</i> 72-75, 80 (July 1993).
	.	Norberg, J. et al., "Glass Transition in DNA From Molecular Dynamics Simulation", <i>Proc. Natl. Acad. Sci. USA</i> 93:10173-10176 (1996)
	.	Notter, R.H., "Physical Chemistry and Physiological Activity of Pulmonary Surfactants", In: <i>Surfactant Replacement Therapy</i> (Eds. Shapiro and Notter, Alan R. Liss, Inc., New York), Chapter 2, pp. 19-71 (1989).
	.	Oksanen et al., "The Relationship between the Glass Transition Temperature and Water Vapor Absorption by Poly(Vinylpyrrolidone)," <i>Pharmaceutical Research</i> 7(6): 654-657 and errata on page 974(1990).
	.	Okumura, K. et al., "Intratracheal Delivery of Calcitonin Dry Powder in Rats and Human Volunteers," <i>S.T.P. Pharmaceutical Sciences</i> 4(I):5 pages (January, February 1994).
	.	Onodera et al., "Glass Transition of Dehydrated Amorphous Solid", <i>Bull. Chem. Soc. Japan</i> 41(9):222 (1968).
	.	Palmer, K.J., et al., "X-Ray Diffractometer and Microscopic Investigation of Crystallization of Amorphous Sucrose", <i>Agricultural and Food Chemistry</i> 4(1): 77-81 (January 1956).
	.	Parks, "Studies on Glass. II The Transition Between the Glassy and Liquid States in the Case of Glucose", <i>Journal of Physical Chemistry</i> 1366-1379 (1928).
<i>APR</i>		Pearlman et al., "Formulation Strategies for Recombinant Proteins: Human Growth Hormone and Tissue Plasminogen Activator", <i>Therapeutic Peptides and Proteins, Formulation, Delivery and Targeting</i> , Cold Spring Harbour, New York, pp. 23-30 (1989).
		Pekarek et al., "Double-walled polymer microspheres for controlled drug release," <i>Nature</i> 367:258-260 (1994). <i>Not Legible</i>
<i>CPL</i>		Phillips, E. et al., "Size Reduction of Peptides and Proteins by Jet-Milling", <i>Respiratory Drug Delivery VI</i> , pp. 161-167 (1998).

Examiner:	Date Considered
<i>Shelley Landau</i>	<i>10/22/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)		Atty. Docket No.:	Application No.:
		0054.10	09/886,296
<b>Information Disclosure Statement By Applicant</b>		Applicant:	
<u>Page 20 of 23</u> <i>(Use Several Sheets if Necessary)</i>		Tarara, et al.	
		Filing Date:	Group:
		June 21, 2001	1616
<b>Other Documents</b>			

<i>401</i>	• Pikal, M. J., "Freeze-Drying of Proteins Part II: Formulation Selections," <i>Biopharm</i> 3(8):26-30 (October 1990).
<i>1</i>	• Pikal, M. J. et al., "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form", <i>Pharmaceutical Research</i> 14(10):1379-1387 (1997).
	• Pikal et al., "Thermal Decomposition of Amorphous $\beta$ -Lactam Antibacterials", <i>Journal of Pharmaceutical Science</i> 66(9): 1312-1316 (September 1977).
	• Pikal, M. J. et al., Errata of "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form," <i>Pharmaceutical Research</i> 15(2):362-363 (1998).
	• Pine, S. H. et al., "15-3 Oligosaccharides and Polysaccharides," <i>Organic Chemistry</i> , 4a' edition. McGraw-Hill International Book Company, page 763 (1980).
	• Pisecky, J., "2. Evaporation and Membrane Filtration", <i>Handbook of Milk Powder Manufacture</i> , Niro A/S, Denmark, page 3 (1997).
	• Pocchiari, M. et al., "Amphotericin B: A Novel Class of Antiscrapie Drugs," <i>J Infect. Dis.</i> 160(5):795-802 (November 1989).
	• Prestrelski, S. J. el al., "Optimization of Lyophilization Conditions for Recombinant Human Interleukin-2 by Dried-State Conformational Analysis Using Fourier-Transform Infrared Spectroscopy," <i>Pharmaceutical Research</i> 12(9):1250-1259 (1995).
	• Prestrelski, S. J. et al., "Separation of Freezing- and Drying-Induced Denaturation of Lyophilized Proteins Using Stress-Specific Stabilization," <i>Archives of Biochemistry and Biophysics</i> 303(2):465-473 (June 1993).
	• "Aerosols, Metered-Dose Inhalers, and Dry Powder Inhalers", <i>Pharmacopeial Previews</i> , 22(6): 3065 (1996).
	• Quan. C. <i>Protein Science</i> 4(2):148, Abstract No. 490-T (1995)
	• Ramanujam, R. et al., "Ambient-Temperature-Stable Molecular Biology Reagents," <i>Biotechniques</i> 14(3):470-473 (1993).
	• Roos, "Phase Transitions of Mixtures of Amorphous Polysaccharides and Sugars," <i>Biotechnology Progress</i> 7(I): 49-53 (1991).
	• Rosen, <i>Surfactants and Interfacial Phenomena</i> ", Second Edition, John Wiley & Sons, New York, pp. 326-329 (1989).
	• Roser, et al., "A Sweeter Way To Fresher Food" <i>New Scientist</i> pp. 25-28 (May 15, 1993).
	• Roser, B., "Trehalose, A New Approach To Premium Dried Foods," <i>Trends in Food Sci. and Tech.</i> pp. 166-169 (July 1991).
	• Roser, B., "Trehalose Drying: A Novel Replacement For Freeze Drying" <i>Biopharm</i> 4:47-53 (1991).
	• Sacchetti, et al., "Spray-Drying and Supercritical Fluid Particle Generation Techniques", <i>Inhalation Aerosols: Physical and Biological Basis for Therapy</i> , A.J. Hickey, ed., Marcel Dekkar, New York, Chapter 11, p. 337 (1996).
<i>261</i>	• Saleki-Gerhardt, A. et al., "Non-Isothermal and Isothermal Crystallization of Sucrose From the Amorphous State," <i>Pharmaceutical Research</i> 11 (8):1166-1173 (1994).

Examiner	Date Considered
<i>Julie D. Landau</i>	<i>10/21/07</i>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0054.10	<b>Application No.:</b> 09/886,296
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b> Tarara, et al.	
<u>Page 21 of 23</u> (Use Several Sheets if Necessary)		<b>Filing Date:</b> June 21, 2001	<b>Group:</b> 1616
<b>Other Documents</b>			

<i>tar</i>	Saleki-Gerhardt, A. et al., "Hydration and Dehydration of Crystalline and Amorphous Forms of Raffinose," <i>Journal of Pharmaceutical Sciences</i> , 84(3):318-323 (March 1995).
<i>tar</i>	Sambrook, et al., <u>Molecular Cloning: A Laboratory Manual</u> , 2nd. ed., "CONCENTRATING NUCLEIC ACIDS: Precipitation with Ethanol or Isopropanol", pp. E.10-E.17, Cold Spring Harbor Laboratory Press (1989).
<i>tar</i>	Sanchez, J. et al., "Recombinant System for Overexpression of Cholera Toxin B Subunit In <i>Vibrio cholerae</i> as a Basis for Vaccine Development" <i>Proc. Natl. Acad. Sci. USA</i> 86:481-485 (1989).
<i>tar</i>	Sarkar and Moore, "Immunization of Mice Against Murine Mammary Tumor Virus Infection and Mammary Tumor Development," <i>Cancer Research</i> 38:1470-1472 (1978).
<i>tar</i>	Schamblin and Zografi, "Enthalpy Relaxation in Binary Amorphous Mixtures Containing Sucrose", <i>Pharmaceutical Research</i> 15(12): 1828-1834 (December 1998).
<i>tar</i>	Schebor, C. et al., "Color Formation Due to Non-Enzymatic Browning in Amorphous, Glassy, Anhydrous, Model Systems", <i>Food Chemistry</i> 65:427432 (1999).
<i>tar</i>	Sciarrà et al., "Aerosols", <i>Remington's Pharmaceutical Sciences</i> , Chap. 93, 17 <sup>th</sup> Ed., Mack Publishing Company, Alfonso R. Gennaro, editor, pp. 1662-1677 (1985).
<i>tar</i>	Sehatlu, T. et al., "Assessment of the Degree of Disorder in Crystalline Solids by Isothermal Microcalorimetry," <i>International Journal of Pharmaceutics</i> 104:135-144 (1994).
<i>tar</i>	Sellers, S. P. et al., "Dry Powders of Stable Protein Formulations From Aqueous Solutions Prepared Using Supercritical CO <sub>2</sub> -Assisted Aerosolization", <i>Journal of Pharmaceutical Sciences</i> , 90(6): 785-797 (2001).
<i>tar</i>	Serajuddin, A. T. M. et al., "Effect of Thermal History on the Glassy State of Indapamide," <i>J. Pharm. Pharmacol.</i> 38:219-220 (1986).
<i>tar</i>	Shalaev, E. Y. et al., "How Does Residual Water Affect The Solid-State Degradation of Drugs in the Amorphous State", <i>Journal of Pharmaceutical Sciences</i> , 85(11): 1137-111 (1996).
<i>tar</i>	Shalaev, E.Y. et al., "Structural Glass Transitions and Thermophysical Processes in Amorphous Carbohydrates and Their Supersaturated Solutions," <i>J. Chem. Soc. Faraday Trans.</i> 91(10):1511-1517 (1995).
<i>tar</i>	Singer et al., "Thermotolerance in <i>Saccharomyces cerevisiae</i> : the Yin and Yang of Trehalose", <i>Tibtech</i> 16:460-468. (1998).
<i>tar</i>	Skrabanja et al., "Lyophilization of Biotechnology Products" <i>PDA J. Pharm. Sci. Technol.</i> 48(6):311.
<i>tar</i>	Slade and Levine, "The Glassy State Phenomenon in Food Molecules," <i>The Glassy State in Foods</i> , Blanshard & Lillford, editors: 35-101 (1993).
<i>tar</i>	Slade and Levine, "Non-Equilibrium Behavior of Small Carbohydrate-Water Systems," <i>Pure and Applied Chemistry</i> , 60(12): 1841-1864 (1988).
<i>tar</i>	Sokolov et al., "Glassy Dynamics in DNA: Ruled by Water of Hydration" <i>Journal of Chemical Physics</i> 110(14):7053-7057 (1999).

<b>Examiner:</b> <i>S. D. Landau</i>	<b>Date Considered:</b> <i>10/27/07</i>
---	--

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0054.10	<b>Application No.:</b> 09/886,296
<b>Information Disclosure Statement By Applicant</b> <u>Page 22 of 23</u> (Use Several Sheets if Necessary)		<b>Applicant:</b> Tarara, et al.	
		<b>Filing Date:</b> June 21, 2001	<b>Group:</b> 1616
<b>Other Documents</b>			

✓	-	Sola-Penna, Mauro et al., <i>Stabilization Against Thermal Inactivation Promoted by Sugars on Enzyme Structure and Function: Why is Trehalose More Effective Than Other Sugars?</i> 360(I) ARCHIVES OF BIOCHEMISTRY AND BIOPHYSICS 10-14, Article No. BB9809606, (December 1998).
✓	✓	Stribling, R. et al., "Aerosol Gene Delivery in Vivo," <i>Proc. Natl. Acad. Sci.</i> 89:11277-11281 (December 1992).
✓	✓	Strickley, R. G. et al., "Solid-State Stability of Human Insulin II. Effect of Water on Reactive Intermediate Partitioning in Lyophiles from pH 2-5 Solutions: Stabilization Against Covalent Dimer Formation", <i>Journal of Pharmaceutical Sciences</i> 86(6):645-653 (1997).
✓	✓	Strom, A. R. and Kaasen, L. "Trehalose Metabolism in Escherichia coli: Stress Protection and Stress Regulation of Gene Expression", <i>Molecular Microbiology</i> 8(2):205-210 (1993).
✓	✓	Stubberud, L. et al., "The Use of Gravimetry For The Study of the Effect of Additives on the Moisture-Induced Recrystallisation of Amorphous State", <i>International Journal of Pharmaceutics</i> 163:145-156 (1998).
✓	✓	Sukenik et al., "Enhancement of a Chemical Reaction Rate by Proper Orientation of Reacting Molecules in the Solid State", <i>J. Am. Chem. Soc.</i> 97: 5290-5291 (September 1975).
✓	✓	Sussich, F. et al., "Reversible Dehydration of Trehalose and Anhydrobiosis: From Solution State to an Exotic Crystal?", <i>Carbohydrate Research</i> 334:165-176 (2001).
✓	✓	Takahashi et al., "Induction of CD8+ cytotoxic T cells by immunization with purified HIV-1 envelope protein in ISCOMs", <i>Nature</i> 344:873-875 (April 1990).
✓	✓	Tarelli, E. et al., "Additives to Biological Substances. 111. The Moisture Content and Moisture Uptake of Commonly Used Carrier Agents Undergoing Processing Conditions Similar to Those Used in the Preparation of International Biological Standards," <i>Journal of Biological Standardization</i> 15:331-340 (1987).
✓	✓	Timko et al., "Thermal Analysis Studies of Glass Dispersion Systems", <i>Drug Devel. Ind. Pharm.</i> 10:425451 (1984).
✓	✓	Timsina, T. et al., "Drug Delivery to the Respiratory Tract Using Dry Powder Inhalers," <i>International Journal of Pharmaceutics</i> 101:1-13 (1994).
✓	✓	To et al., "Collapse. a Structural Transition in Freeze Dried Carbohydrates", <i>J. Fd. Technol.</i> 13: 567-581 (1978).
✓	✓	Toyama, A. (ed) <i>Handbook of Natural Product for food processing</i> , 9th Edition, Osaka, Japan, Shokuhin to Kagaku Sha, pages 384 and 495 (ISBN4-87994-048-8), (1986).
✓	✓	Tsouroufis, S. et al., "Loss of Structure in Freeze-Dried Carbohydrates Solutions: Effect of Temperature, Moisture Content and Composition," <i>J. Sci. Fd. Agric.</i> 27:509 519 (1976).
✓	✓	Underwood et al., "A Novel Technique for the Administration of Bronchodilator Drugs Formulated as Dry Powders to the Anaesthetized Guinea Pig", <i>J. of Pharmacological Methods</i> , Vol. 26, pp. 203-210, 1991.
✓	✓	Uritani, M. et al., "Protective Effect of Disaccharides on Restriction Endonucleases During Drying Under Vacuum." <i>J. Biochem.</i> 117:774-779 (1995).

<b>Examiner:</b> <i>J. D. Tarara</i>	<b>Date Considered</b> <i>10/27/07</i>
---	---

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0054.10	<b>Application No.:</b> 09/886,296
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b> Tarara, et al.	
<u>Page 23 of 23</u> <i>(Use Several Sheets if Necessary)</i>		<b>Filing Date:</b> June 21, 2001	<b>Group:</b> 1616
<b>Other Documents</b>			

<i>Star</i>	-	Vain et al., "Development of the particle inflow gun", <i>Plant Cell, Tissue and Organ Culture</i> 33:237-246 (1993).
	-	Vavelyuk, O.L. et al., "Thermostability of DNA and Its Association with Vitrification", <i>Tsitolgiya</i> 41(11):958-965 (1999).
	-	Vidgrén, M. T. et al., "Comparison of Physical and Inhalation Properties of Spray-Dried and Mechanically Micronized Disodium Cromoglycate," <i>International Journal of Pharmaceutics</i> 35:139-144 (1987).
	-	Vromans, H. et al., "Studies on Tabletting Properties of Lactose. VII. The Effect of Variations in Primary Particle Size and Percentage of Amorphous Lactose in Spray Dried Lactose Products," <i>International Journal of Pharmaceutics</i> 35:29-36 (1987).
	-	Wang, et al. eds. <u>Stability and characterization of protein and peptide drugs</u> , Table of Contents, 6 pages (1993).
	-	Welsh, D. T., "The Role of Compatible Solutes In the Adaptation and Survival of Escherichia coli," Ph.D. Thesis Submitted to Department of Biological Sciences, University of Dundee. pp. 1-262 . (August 1992).
	-	Whittier, E., "Lactose and its Utilization: A Review," <i>J. Dairy Sci.</i> 27(7)505-537 (July 1994).
	-	William and Leopold, "The Glassy State in Com Embryos" <i>Plant Physiology</i> 89:977-981 (1979).
	/	Williams et al., "The Temperature Dependence of Relaxation Mechanisms in Amorphous Polymers and Other Glass Forming Liquids", <i>The Journal of the American Chemical Society</i> 77: 3701-3707 (1955).
	-	Wolff, J. A. et al., "Grafting Fibroblasts Genetically Modified to Produce L-Dopa in a Rat Model of Parkinson Disease," <i>Proc. Natl. Acad. Sci.</i> 86:9011-9014 (November 1989).
	-	Xi, Y. G. et al., "Amphotericin B Treatment Dissociates in Vivo Replication of the Scrapie Agent From PrP Acummulation", <i>Nature</i> 356:598-601 (April 1992).
	-	York, "Powdered Raw Materials: Characterizing Batch Uniformity," <i>Respiratory Drug Delivery IV, Programs and Proceedings</i> , edited by Byron, Dalby and Farr: 83-91 (1994).
	-	Yoshida, H. et al., "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form," <i>Journal of Pharmaceutical Sciences</i> 68(5): 670-671 (May 1979).
	-	Yoshioka, M. el al., "Crystallisation of Indomethacin From the Amorphous State Below and Above Its Glass Transition Membrane," <i>Journal of Pharmaceutical Sciences</i> 83(12):1700-1705 (December 1994).
	-	Zubay, G. <i>BIOCHEMISTRY</i> , SECOND EDITION, pages 39 & 169, Table 5-6 Major Steroid Hormones (1988).
	-	Zubay, G. <i>BIOCHEMISTRY</i> , SECOND EDITION, pages 216-232 "Structural Properties of DNA" (1988).
	-	Nektar U.S. Patent Application No. 08/044,358, "Compositions and Methods For Nucleic Acid Delivery To The Lung" filed by Patton et al. on April 7, 1993, assigned to Inhale Therapeutic Systems.
<i>Star</i>	-	Nektar U.S. Patent Application No. 08/422,563, filed April 14, 1995, Paper No. 17, Office communication mailed April 3, 1998 (Patent No. 5,994,314).

<b>Examiner:</b> <i>Dr. M. Standard</i>	<b>Date Considered:</b> <i>10/27/07</i>
--	--

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.